UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,025	02/23/2006	Francoise Russo-Marie	3665-165	7976

23117 7590 05/16/2006

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/560,025	RUSSO-MARIE ET AL.	
	Examiner	Art Unit	
	Christina Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-18 were canceled by Applicant; claims 19-36 are pending. Claims 20-36 are dependent on cancelled claims. For the purpose of determining if claims 19-36 lack a unity of invention, it is assumed, based on a comparison of the cancelled and pending claims, that reference to the cancelled claim x, means reference to the pending claim y: x,y; 2, 20; 3, 21; 4, 22; 5, 23; 6, 24; 7, 25; 8, 26; 9, 27; 10, 28; 11, 29; 12, 30; 13, 31; 14, 32; 15, 33; 16, 34; 17, 35; and 18,36. Correction is required.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 19-25, 27 and 29-32, drawn to a therapeutic compound joined to a targeting segment by a cleavable linker, link Groups I-XXXIII.

Group I, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 23.

Group II, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 24.

Group III, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 25.

Group IV, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 26.

Group V, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 27.

Group VI, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 28.

Group VII, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 29.

Group VIII, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 30.

Group IX, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 31.

Group X, claim(s) 26 in part, drawn to a targeting segment comprising SEQ ID NO: 32.

Group XI, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 1.

Group XII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 2.

Group XIII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 3.

Group XIV, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 4.

Group XV, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 5.

Group XVI, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 6.

Group XVII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 7.

Group XVIII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 8.

Group XIX, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 9.

Group XX, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 10.

Group XXII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 11.

Group XXIII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 12.

Group XXIV, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 13.

Group XXV, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 14.

Group XXVI, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 15.

Group XXVII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 16.

Group XXVIII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 17.

Group XXIX, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 18.

Group XXX, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 19.

Group XXXI, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 20.

Group XXXII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 21.

Group XXXIII, claim(s) 28 in part, drawn to a targeting segment comprising SEQ ID NO: 22.

Claims 33 and 34, drawn to a pharmaceutical composition and a method of treating disease, respectively, link Groups XXXIV and XXXV.

Group XXXIV, claim(s) 35, drawn to a method of treating cancer.

Group XXXV, claim(s) 36, drawn to a method of treating an inflammatory disease.

5. The inventions listed as Groups I-XXXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons described below.

6. The claims are drawn to a molecule comprising three segments: C, capable of targeting the molecule to membranes of cells engaged in an apoptotic process; A, a therapeutic compound; and L, a linker susceptible to cleavage in the cell undergoing apoptosis. Buggy (USPN 6,875,598) teaches therapeutic compounds conjugated to antibodies designed to target apoptotic cells (see column 43, lines 23-31). Goers *et al.* (USPN 4,867,973) teach antibodies joined to therapeutic agents via cleavable linkers (see column 3, lines 5-16). Therapeutic compounds conjugated to targeting molecules by cleavable linkers, and molecules capable of targeting apoptotic cells do not define a contribution over the prior art. Thus, there is a lack of unity *a posteriori.* See MPEP § 1850.

7. Claims 19-25, 27 and 29-32 link Groups I-XXXIII. Claims 26 and 28, drawn to targeting segments, are distinct inventions because they lack a special technical feature as described above. Claim 26 is drawn to a targeting segment selected from the group consisting of variants of human annexin, SED ID NOs: 23-32. The compounds of claim 26 have a common activity (targeting the fusion molecule to apoptotic cells) and a common structure (sequence homology to human annexin). Therefore, claim 26 is drawn to a Markush grouping of alternative chemical compounds.

8. Claim 28 is drawn to a targeting segment selected from the group consisting of variants of human coagulation factors and β2-Glycoproteins, SED ID NOs: 1-22. The compounds of claim 28 have a common activity (targeting the fusion molecule to apoptotic cells) and a common structure (targeting molecule joined to a therapeutic compound via cleavable linker). Within these alternative chemical compounds exists five additional groups with a common activity (targeting the fusion molecule to apoptotic cells) and a common structure (sequence homology to the type C1 domain of human coagulation factor V (SEQ ID NOs:1-4), sequence homology to the type C1 domain of human coagulation factor VIII (SEQ ID NOs:5-8), sequence homology to the type C2 domain of human coagulation factor V (SEQ ID NOs:9-12), sequence homology to the type C2 domain of human coagulation factor VIII (SEQ ID NOs:13-16), and sequence homology to human β2-Glycoproteins (SEQ ID NOs:17-22)). Therefore, claim 28 is drawn to a Markush grouping of alternative chemical compounds.

9. Claims 33 and 34, drawn to a pharmaceutical composition and a method of treating disease, respectively, link Groups XXXIV and XXXV. Claims 35 and 36 lack a special technical feature as described above and are drawn to methods of treating distinct populations, cancer and inflammatory diseases, respectively.

Species Election

10. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

11. The species are as follows: the molecule of claim 19 comprising three segments, a targeting segment, a therapeutic segment and a linker.

12. No matter which group is elected, Applicant is required, in reply to this action, to elect a single species (i.e. a SEQ ID NO for the targeting segment C, and a fully defined amino acid sequence or chemical structure for the linker and therapeutic segment A) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. The claims are deemed to correspond to the species listed above in the following manner: they have distinct chemical structures.

15. The following claim(s) are generic: 19-36.

16. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are alternative chemical compounds of a Markush group having a common activity (delivery of a

therapeutic compound to an apoptotic cell) and a common structure (the SEQ ID NO specific to the group).

Conclusion

17. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

18. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

19. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (517) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

cmb

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600